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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/813,990	03/22/2001	Minako Hijikata	205057US0SRD	2667

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EXAMINER	
CHAKRABARTI, ARUN K	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 05/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/813,990	Applicant(s) Hijikata
	Examiner Arun Chakrabarti	Art Unit 1634

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Mar 25, 2003*.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *18-61* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *18-24 and 46* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *25-45 and 47-61* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. *09/813,990*.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). ___
4) ☐ Interview Summary (PTO-413) Paper No(s). ___
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Detailed Action*

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group I, corresponding to claims 18-24, and 46, in Paper No. 0303 is acknowledged. The traversal is on the ground(s) that office has not provided sufficient reasons and/or examples to show how the separate utility of one Group is materially different than other groups. This is not found persuasive because structurally different nucleic acids are inherently capable of producing different proteins and any 11 and 15 mer nucleotides similar to SEQ ID numbers 1-4 as claimed in the independent claims of all groups are capable of producing proteins having separate utilities. This argument is sufficiently supported by the current rejection based on Krol et al. (Microbiology, (1997), Vol. 143, pages 1389-1394) and Cross et al. (Nature Genetics, (1994), Vol. 6, pages 236-244), which demonstrate separate utilities of those nucleotides. Moreover, search of three more SEQ ID Nos: 2-4 in addition to SEQ ID NO: 1 is prima facie burden of search, which is not rebutted.

The requirement is still deemed proper and is therefore made FINAL.

Specification

2. Claim 24 is objected to because of the following informalities: Claim 24 recites the word "domein" on line 6 of the claim . Appropriate correction is required by changing it to "domain".

35 U.S.C. 112, Written Description Rejection

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 18-24, and 46 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discloses SEQ ID NO: 1 which corresponds to the promoter region of the MXA gene of human species. Claims 18, 20, 23, and 24 are directed to encompass any deletions, substitutions or additions at positions except for the 455 th position of SEQ ID NO: 1, which is virtually any gene sequences, sequences that hybridize to SEQ ID NO: 1, corresponding sequences from other species, mutated sequences, allelic variants, splice variants, sequences that have a recited degree of identity (any degree of similarity, and homology), and so forth. None of these sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry,

whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of SEQ ID NO: 1, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is

claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood* , 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel* , 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

Therefore, only SEQ ID NO: 1 but not the full breadth of the claim (or none of the sequences encompassed by the claim) meets the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written

description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.).

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 18, 20, 21, 23, 24, and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Krol et al. (Microbiology, (1997), Vol. 143, pages 1389-1394).

This rejection is based on the fact that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. In this case, any polynucleotide, which meets the structural limitation of the instant claims is inherently capable of performing the intended use of predicting the efficacy of interferon therapy using interferon-alpha and/or interferon-beta for treating an individual who suffers from hepatitis C virus.

Krol et al teaches a polynucleotide derived from SEQ ID NO:1 by inclusion of several deletions, substitutions or additions at positions except for the 455th position and also teaches a polynucleotide containing the sequence which spans from 441st to the 455th position of SEQ ID NO:1 (Genbank Accession NO: U44387 and X98117, and bases 1 to 4423, a copy of SEQ ID search enclosed herewith).

Krol et al. inherently teaches a polynucleotide further comprising at least one additional polynucleotide connected to the polynucleotide as described above, the additional polynucleotide being selected from a transmembrane domain (Figure 2, overlined regions).

Krol et al. inherently teaches a vector comprising the above nucleotides (Results and Methods Sections)

7. Claims 18, 20, 22, 23, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Cross et al. (Nature Genetics, (1994), Vol. 6, pages 236-244).

This rejection is based on the fact that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. In this case, any polynucleotide, which meets the structural limitation of the instant claims is inherently capable of performing the intended use of predicting the efficacy of interferon therapy

using interferon-alpha and/or interferon-beta for treating an individual who suffers from hepatitis C virus.

Cross et al teaches a polynucleotide derived from SEQ ID NO:1 by inclusion of several deletions, substitutions or additions at positions except for the 455th position and also teaches a polynucleotide containing the sequence which spans from 449th to the 459th position of SEQ ID NO:1 (Genbank Accession NO: Z63622, and bases 1 to 160, a copy of SEQ ID search enclosed herewith).

Cross et al inherently teaches a polynucleotide further comprising at least one additional polynucleotide connected to the polynucleotide as described above, the additional polynucleotide being selected from a promoter or enhancer (Figures 1, 4, and 7).

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph. D., whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119. The fax phone number for this Group is (703)746-4979.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group analyst Chantae Dessau whose telephone number is (703) 605-1237.

Arun Chakrabarti,

ARUN K. CHAKRABARTI
PATENT EXAMINER

Patent Examiner,

April 16, 2003